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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,847	11/30/2005	Fyodor Urnov	8325-0034 (S34-US1)	7879

20855 7590 05/12/2011

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EXAMINER	
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ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
05/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,847	URNOV ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1 and 6-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 January 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1 and 6-15 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01 August 2007.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-5 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. As set forth in *In re Alonso* 88 USPQ2d 1849 (Fed. Cir. 2008), at 1851:

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention …." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997); *see also LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005); *Eiselstein v. Frank*, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 1995).

Alonso at 1852:

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo*, 323 F.3d at 964.

5. In applying the test as set forth in *Alonso*, it is noted that applicant is claiming "[a]n array comprising a plurality of polynucleotide sequences" wherein the array comprises polynucleotides that are "100 to 300 base pairs in length, wherein each polynucleotide sequences [*sic*] comprises an accessible region of cellular chromatin."

6. A review of the disclosure finds that a Sequence Listing was filed on 17 November 2005. Said Sequence Listing, however, has been found to comprise but a single sequence, and then the sequence depicted is that of 25 amino acids of an indeterminate composition, not of multiple nucleic acids that are derived from "accessible regions of cellular chromatin and are isolated based on their altered reactivity to probe of chromatin structure." For convenience, the sole disclosed sequence is reproduced below.

```
<400> SEQUENCE: 1
      Cys Xaa Xaa Xaa Xaa Cys Xaa Xaa Xaa Xaa Xaa Xaa Xaa Xaa Xaa Xaa Xaa
      1               5                   10                  15
      Xaa Xaa His Xaa Xaa Xaa Xaa Xaa His
                  20                  25
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7. While the claimed invention is defined in terms of the process used to isolate it, and not in terms of its nucleotide structure, the specification similarly fails to describe the composition of the probe(s) that are used to isolate the members of the array.

8. As presently worded, the claimed array can comprise "available" nucleic acids that are derived from any life form as well as variants of same. In support of this position, attention is directed to page 8, last paragraph, of the specification, which states in part:

> Unless otherwise indicated, a particular nucleic acid sequence also implicitly encompasses conservatively modified variants thereof (e.g., degenerate codon substitutions) and complementary sequences, as well as the sequence explicitly indicated.

9. A review of the disclosure fails to find where any array of any nucleic acids, real or prophetic, has been prepared, regardless of the accessibility of the nucleotide sequence.

10. For purposes of examination, the array of polynucleotide sequences has been construed as encompassing at the very least, two nucleic acids molecules. A review of the disclosure has fails to identify where applicant has prepared any array, including an array that has two nucleic acids molecules, be they accessible or not.

11. While the specification explicitly allows for the inclusion of variants, the specification has not been found to provide an adequate written description of those nucleic acid molecules that are useful versus those that are not.

12. The absence of an adequate written description for any such array does not reasonably suggest that applicant had possession of the array at the times of filing.

13. The case at hand is analogous to *Fiers v. Sugano* 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject *Fiers* argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a

> conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

14. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

15. For the above reasons, and in the absence of convincing evidence to the contrary, claims 2-5 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

16. At page 8, bridging to page 9, of the response of 24 February 2010, argument is presented that applicant need only provide a description of the novel aspect of the claimed invention, which is the method by which the array is produced, and not the nucleic acids to be found thereon.

17. The above argument has been considered and has not been found persuasive. The claims under consideration are drawn to a product. While the claim format has been shifted to where it

is a product-by-process, the claims are still drawn to a product. The claimed product is not limited to that which was known or to that which has utility. Rather, the claims encompass a broad genus of nucleic acids. The disclosure of but a single species of nucleic acid is not considered to be a representative showing to demonstrate that applicant had possession of the entire genus of nucleic acids at the time of filing.

18. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

19. Claims 2-5 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

20. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' "Genentech, *Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth

> as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary

The quantity of experimentation necessary is great, on the order of several man-years, and then with little if any reasonable expectation of successfully enabling the full scope of the claims.

The amount of direction or guidance presented,

The amount of guidance provided is limited, generally prophetic, and not commensurate with the scope of the claims. The specification does not set forth any array, much less a method of using same.

The presence or absence of working examples

The specification comprises the following examples:

- Example 1: Preparation of regulatory DNA library from HEK 293 cells, pp. 61-62. In this example, total nuclear DNA was isolated, restricted, and inserted into a plasmid. Applicant reports that 40,000 – 50,000 clones were obtained.
- Example 2, Analysis of Selected Clones, pp. 62-66. 1% of the clones from Ex. 1 were evaluated.
- Example 3: Identification of target sequences of Estrogen Receptor (ER), pp. 66-67; and

- Example 4: Analysis of Drug Effects, pp. 67-68. DNA from estrogen treated and untreated cells were hybridized to regDNA chips. The composition, source and manner of making the chips are not disclosed.

None of the examples is directed to the identification of nucleic acid molecules that corresponds to accessible regions of cellular chromatin and is isolated based on their altered reactivity to probe of chromatin structure, and which are each individually isolated and bound to a distinct address on a solid support.

It is further noted that none of the examples teach how the claimed array is to be used in a method that has utility. While the elected invention is drawn to an array and not to a method of use, the specification must still enable the making and use of the invention. In the present case, the specification has not been found to do either. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> "'[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

The nature of the invention and the breadth of the claims

The invention relates generally to arrays of nucleic acids where each nucleotide sequence is located at a distinct address on a solid support. The nucleic acids are characterized in that, they correspond to accessible regions of cellular chromatin and are isolated based on an unspecified altered reactivity to probing of chromatin structure.

The members of the array can be of virtually any length, and at any density.

The array fairly encompasses nucleic acids that are derived from any life form.

The state of the prior art and the predictability or unpredictability of the art

The art to which the invention relates, *i.e.*, nucleic acid array art and hybridization art, has advanced to the point that certain problematic areas have been identified. In support of this position as it relates to the manufacture and use of oligonucleotide arrays, US Patent 6,077,674 (Schleifer et al.) addresses certain highly problematic areas:

> While in situ synthesis is a very flexible means for producing DNA arrays, the fidelity or percentage of full-length oligonucleotides synthesized within a feature on the array is less than 100 percent. An ideal array will have only full-length oligonucleotides attached to each feature. The ideal array promotes accuracy in hybridization experiments or assays or target biological materials. If the fidelity of an in situ generated array is less than 100 percent, it typically has non full-length oligonucleotides within a feature that usually consists of shorter lengths of the correct sequence, and to a lesser degree, incorrect sequences. Typical DNA coupling efficiencies are around 97 to 99 percent for the standard phosphoramidite chemistry. For oligonucleotides that are 25 nucleotides in length, these efficiencies result in only 46 to 77 percent full-length oligonucleotides contained within a feature (0.97^{25} to 0.99^{25}). This loss of fidelity can cause chemical noise in hybridization conditions. The loss of fidelity can also lead to difficulty in interpreting the data.
>
> Photolithography is a method used by Affymetrix in California to produce in situ arrays using procedures that are similar to those used in the semi-conductor industry. In procedure described by Fodor et al. from Affymetrix U.S. Pat. No. 5,405,783, a photo-deprotection step is used where the protecting group on the phosphoramidite is removed by exposing a photosensitive protecting group to light. Four photo masks are used to create patterns to de-protect areas of the substrate and then a nucleotide is added to these regions. This technique requires four masks for each layer of nucleotides. While this technique allows for the production of high-density oligonucleotide arrays, it is less efficient than traditional phosphoramidite synthesis chemistry. With efficiencies of about 90 to 95 percent, the percentage of full-length oligonucleotides within a feature is further reduced to about 9 to 27 percent for oligonucleotides that are 25 nucleotides long (0.90^{25} to 0.95^{25}).

At column 40 of Jones (US Patent 5,858,671) the inherent obstacle in synthesizing oligonucleotide arrays is disclosed. As stated therein, "that even if the constituent enzymatic steps approach 100% completion, incompletely processed products can accumulate to significant levels. For example, during oligonucleotide synthesis of a 70-mer, requiring 69 couplings, a 99% coupling efficiency results in only 50% of the generated oligonucleotides being full length ($0.99^{69} = 0.50$)." In the present case, applicant is claiming a product that would be the result of an infinite number of couplings, not just 69 as described above.

As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known

> scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

21. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

Response to argument

22. At page 9, bridging to page 10, of the response of 24 February 2010 argument is presented that the claimed invention is fully enabled and that the claimed invention does not suffer from the art-recognized problems. In support of this position, applicant asserts that the array is synthesized using methods disclosed in other patents.

23. The above argument has been considered and has not been found persuasive as applicant is arguing limitations not recited in the pending claims that are under consideration.

24. It is noted that applicant has not addressed the basis of the rejection that the specification does not enable the use of the array in a method that has utility under 35 USC 101. Applicant's failure to address this issue is taken as tacit agreement with same.

25. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

26. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

27. Claims 2-5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

28. It is noted with particularity that the claimed array is defined in terms of a product-by-process. While such claim format is permissible, the claim must still be directed to a product that has utility. However, not all nucleic acids have utility. An example of such are expressed sequence tags (ESTs) for which no known utility exists. The claimed array does not differentiate between those nucleic acids that do and do not have utility.

29. Acknowledgement is made of where applicant has provided a listing of potential utilities at page 53 of the specification. Such asserted utilities are not deemed to be specific to the members of the array.

30. It matters not whether the claim is drawn to a product or process; the claim must be drawn to an invention that satisfies the utility requirements as set forth under 35 USC 101 and as further developed in the Utility Guidelines. In support of this position, attention is directed to *Brenner, Comr. Pats. v. Manso*n, 148 USPQ 689 (US Sup Ct 1966):

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, 22 without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
>
> * * *

> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. 24 That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

31. Claims 2-5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to argument

32. At page 10, bridging to page 11, of the response, argument is presented that the claimed array does have utility, citing a passage of the specification that, "it possible, for the first time, to prepare a microarray of human regulatory sequences."

33. The above argument has been considered and has not been found persuasive as the claims are not limited to human DNA, much less human regulatory sequences, but rather, fairly encompass any "accessible region of cellular chromatin" where any definition of "accessible' is applied to "chromatin" derived from any cell, including artificial constructs produced in a lab which have no known utility under 35 USC 101.

34. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

35. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

36. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

37. The term "accessible regions" in claim 2 is a relative term which renders the claim indefinite. The term "accessible regions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Acknowledgement is made of the specification providing a definition of the terms at page 12. Said definition, however, is exemplary and not binding. Accordingly, the metes and bounds of the claim cannot be readily determined.

Response to argument

38. At page 11-12 of the response argument is presented that the term/expression is definite. In support of this position applicant reproduces a passage found at page 24, line 29, bridging to page 25, line 8.

39. Applicant's argument, including the cited passage, has been considered and has not been found persuasive towards the withdrawal of the rejection. While the specification does provide a definition, the definition is found to be exemplary and not limiting. In support of this position, it is noted that the passage states, "an accessible region includes, but is not limited to…" It is precisely that one does not know the limits that one cannot readily determine the metes and bounds of the array.

40. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claim Rejections - 35 USC § 102

41. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

42. Claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,350,618 B1 (Borrelli et al) in view of applicant's admissions.

43. Attention is directed to MPEP 2129 [R-6], Admissions as Prior Art, which states in part:

> I. ADMISSIONS BY APPLICANT CONSTITUTE PRIOR ART
> A statement by an applicant >in the specification or made< during prosecution identifying the work of another as "prior art" is an admission **>which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988).

44. As a result of amendment, claims 2-5 are drawn to an array, which is defined in terms of a product-by-process of making. With respect to product-by-process claims, it is "well settled that the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318 (Fed. Cir. 2006) (quoting *In re Stephens*,

345 F.2d 1020, 1023 (CCPA 1965). As stated in *In re Thorpe*, 777 F.2d 695,697 (Fed. Cir. 1985) (citations omitted):

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

45. Claim 2, line 1, states; "[a]n array comprising…" Accordingly, the array has been construed as encompassing not only the recited polynucleotides, but additional sequences, even in significant amounts.

46. For purposes of examination, the expression "accessible regions of cellular chromatin" has been construed as encompassing not only naturally-occurring chromosomes, but also artificial chromosomes. Further, the aspect of what constitutes "accessible regions" has been construed as encompassing virtually any portion of the chromosome. While page 12 of the specification does provide a definition, said definition is general in terms and not binding. Accordingly, the polynucleotide sequences on the array can be from virtually any source, of any nucleotide composition, including artificial polynucleotide sequences.

47. Borrelli et al., column 1, teach of the production of arrays that comprise all possible oligos of any length N. The aspect that the array can comprise any and all possible nucleotides of a given length is deemed to meet at least one embodiment of the claims.

48. Applicant's representative, at page 9 of the response of 24 February 2010 states:

> Satisfaction of the written description requirement necessitates that subject matter which is novel be described - in this case preparation of polynucleotide sequences such that each polynucleotide comprises an accessible region of cellular chromatin.

Such statements are taken that the method of preparation, not the nucleic acids, are novel.

49. For the above reasons, and in the absence of convincing evidence to the contrary, claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,350,618 B1 (Borrelli et al) in view of applicant's admissions.

Conclusion

50. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571)272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

51. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

52. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634